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| 10/582,637 | 06/12/2006 | Uwe Michelsen | MERCK-3177 | 2067 |
| 23599 7590 04/30/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | | |
| EXAMINER | | | | |
| WILDER, CYNTHIA B | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1637 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/582,637

Applicant(s)

MICHELSSEN ET AL.

Examiner

CYNTHIA B. WILDER

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date 6/12/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The use of the trademarks "Tween", "Triton" at page 6 and 8, "MagPrep" at pages 8-10, "PicoGreen" and Ribopage at page 9 have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-6, 7 and 8 are indefinite at confusing at "characterised by", "characterized in that" and "provision of" because the claims appear to be a literal translation from a foreign document. It is suggested amending the claims to conform to standard US practice.

(b) Claim 4 is indefinite at "such as" because it is unclear whether the limitation following the phrase is part of the claimed invention. See MPEP § 2173.05(d).

(c) Claims 6 and 7 are indefinite at the recitation of the abbreviation "GTC"

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because abbreviations often have more one meaning in the art.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gundling (20020068821, June 2002). Regarding claim 1, Gundling teaches a method for the isolation of RNA from the sample, the method comprising providing a metal oxide support material (0012), wherein said metal oxide support material is a magnetite (Fe_3O_4) (Table 1, 0030) providing a binding buffer which comprises guanidinium thiocyanate in a concentration of between 2M and 10M, more preferably between 3M and 6M, mixing the sample with the metal oxide support material and the binding buffer, where a phosphate concentration which supports the binding of RNA is present in this mixture and isolation of the solid phase with the bound RNA (see Examples 1 and 2).

Regarding claim 2, Gundling teaches wherein the solid phase is optionally washed and the RNA is subsequently eluted from the solid phase (0018).

Regarding claim 3, Gundling teaches wherein the elution is carried out using an elution buffer which facilitates a pH range between 7 and 9 and comprises phosphate (0018).

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Regarding claim 6, Gundling et al teach a kit comprising at least a magnetite solid phase and a binding buffer having a GTC concentration of greater than 3 mol/l (entire patent and 0022).

Regarding claim 8, Gundling et al teach wherein the kit comprises one or more of the following: an elution buffer, a wash buffer or a phosphate salt solution (entire patent and 0022). Therefore, Gundling meets the limitations of the claims recited above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gundling as previously applied above in view of Madden et al (20050054847, effective filing date August 2003). Regarding claims 4 and 7, Gundling et al teach a method and kit for the isolation of RNA from samples wherein the method comprising providing a magnetite solid phase; providing a binding buffer which comprises guanidinium thiocyanate, mixing the sample with the magnetite solid phase and the binding buffer, where a phosphate concentration which supports the binding of RNA is present in the mixture, isolation of the solid phase with the bound RNA and further eluting the RNA from the solid phase.

Gundling do not expressly teach wherein the binding buffer comprises a chelator, such as EDTA in a concentration of between 5 and 200 mmol.

Madden et al teach method and kit for purification of RNA. Madden et al teach an RNA binding buffer which is preferably used in the purification of RNA, said binding buffer comprising from 1 to 9M guanidine isothiocyanate and 25 mM EDTA or another chelating agent, like EDTA (0034 and 0238).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to incorporate a chelating agent, such as EDTA into the RNA isolation method and kit of Gundling, since the combination of the EDTA with the binding buffer of Gundling does not alter the effects of the binding buffer and could be used to predictably achieve the results of purifying RNA in an efficient manner as suggested by Madden.

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9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gundling as previously applied above in view of Kilaas et al (WO 2004/003231, filing date July 2003). Regarding claim 5, Gundling teaches a method for isolating RNA as previously described above, wherein a magnetite solid phase is used in the assay. Gundling do not expressly teach the diameter and specific surface area of the magnetite particles.

Kilaas et al provides a general teaching of magnetic particles for binding a target substance, wherein the target substance is DNA or RNA (page 1 and 10). Kilaas et al teach wherein the magnetic particle has a diameter of 0.1 μm to 100 μm (page 10). Kilaas et al do not expressly teach the specific surface area. However, MPEP states that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, this is particularly true as the specification does not provide any evidence of unexpected resulted using the claimed specific surface area of the magnetite particles.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Patent Examiner
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4/25/2008

